



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: RAMESHWAR, Pranela, *et al.*

APPLICATION No.: 10/628,066

FILED: July 25, 2003

FOR: HUMAN PREPROTACHYKININ GENE PROMOTER

EXAMINER: MISOOK YU

ART UNIT: 1642

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited on March 3, 2004, with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

AMY SHIELDS

INFORMATION DISCLOSURE STATEMENT WITHIN THREE MONTHS OF APPLICATION FILING OR BEFORE FIRST ACTION – 37 C.F.R. § 1.97(b)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. Timing of Submission

This information disclosure is being filed before the mailing of a first Office action on the merits. [37 C.F.R. § 1.97(b)(3)]. The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

☐ Copies of the following references are enclosed:

- ☐ All cited references
- ☐ References marked by asterisks
- ☐ The following:

☒ Copies of the following references can be found in parent U.S. Application No. 09/747,429:

- ☒ All cited references
- ☐ References marked by asterisks
- ☐ The following:

☐ This application was filed after 30 June 2003 and no copies of U.S. patents nor published applications are enclosed (See Notice of Deputy Commissioner Kunin, dated 11 July 2003).

☐ The following references are not in English. For each such reference, the undersigned has enclosed (i) a translation of the reference; (ii) a copy of a

communication from a foreign patent office or International Searching Authority citing the reference, (iii) a copy of a reference which appears to be an English-language counterpart, or (iv) an English-language abstract for the reference prepared by a third party. Applicant has not verified that the translation, English-language counterpart or third-party abstract is an accurate representation of the teachings of the non-English reference, though, and reserves the right to demonstrate otherwise.

- ☐ All cited references
- ☐ References marked by ampersands
- ☐ The following:

3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment

No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.

- ☐ Applicant further submits that no fee is due in light of the following certification under 37 C.F.R. § 1.97(e) (check only one):
 - ☐ In accordance with 37 C.F.R. § 1.97(e)(1), the undersigned hereby states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement; or
 - ☐ In accordance with 37 C.F.R. § 1.97(e)(2), the undersigned hereby states that no item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c), more than three months prior to the filing of this statement.

However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. **50-2586**.

5. **Patent Term Adjustment (37 C.F.R. § 1.704(d))**

- ☐ The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

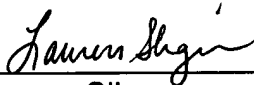
PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:

- ☐ A check in the amount of _____ is enclosed for the above fee(s).
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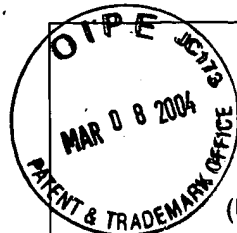
The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Deposit Account No. **50-2586**.

Respectfully submitted,
Perkins Coie LLP

Dated: March 3, 2004

By: 
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Form PTO-1449 (Modified)
(Use several sheets if necessary)

COMPLETE IF KNOWN

Application Number	10/628,066
Confirmation Number	4164
Filing Date	July 25, 2003
First Named Inventor	Pranela Rameshwar
Group Art Unit	1642
Examiner Name	
Attorney Docket No.	54704.8010.US02

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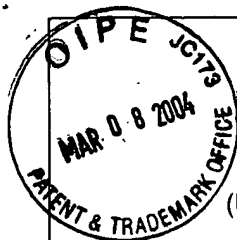
U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear
		NUMBER	Kind Code (if known)			

FOREIGN PATENT DOCUMENTS

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		Office	NUMBER	Kind Code (if known)				
	A1	WO	87/07643	A1		12/17/1987		

EXAMINER	DATE CONSIDERED
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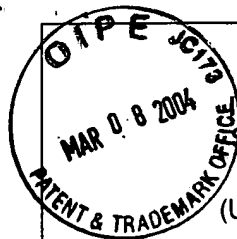
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OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T
	A2	BOST, K.L. and Pascual, D.W., Substance P: a late-acting B lymphocyte differentiation cofactor. <i>Am. J. Physiol.</i> 262:C537-545 (1992).	
	A3	BUNN, P.A. <i>et al.</i> , Effects of Neuropeptide Analogues on Calcium Flux and Proliferation in Lung Cancer Cell Lines. <i>Cancer Research</i> 54:3602-3610 (1994).	
	A4	CREMINS, J.D. <i>et al.</i> , Characterization of Substance P-Like Immunoreactivity and Tachykinin-Encoding mRNAs in Rat Medullary Throid Carcinoma Cell Lines. <i>Journal of Neurochemistry</i> 58:817-824 (1992)	
	A5	EVERARD, M.J. <i>et al.</i> , <i>In vitro</i> effects of substance P analogue (D-Arg ¹ , D-Phe ⁵ , D-Trp ^{7,9} , Leu ¹¹ substance P on human tumour and normal cell growth. <i>British Journal of Cancer</i> 65:388-92 (1992)	
	A6	GENEMBL accession number S69719	
	A7	GILCHRIST et al (DNA Cell Biol 10, 743-749 abstract only)	
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	A9	JONES, D.A. <i>et al.</i> , Processing [D-Arg ¹ , D-Phe ⁵ , D-Trp ^{7,9} , Leu ¹¹] Substance P in Xeograft Bearing Nu/Nu Mice. <i>Peptides</i> 18:1073-1077 (1997)	
	A10	MCGREGOR, G.P. <i>et al.</i> , Preprotachykinin-A Gene Expression Occurs Transiently in the Developing Rat Endocrine Pancreas and Can Be Regulated in RINm5F Cells. <i>Endocrinology</i> 136:2538-2546 (1995)	
	A11	MOORE, R.N. <i>et al.</i> , Substance P Augmentation of CSF-1-Stimulated <i>in vitro</i> Myelopoiesis. <i>The Journal of Immunology</i> 141:2699-2703 (1988)	
	A12	RAMESHWAR, Pranela <i>et al.</i> , <i>NEURAL REGULATION OF HEMATOPOIESIS BY THE TACHYKININS, Implications for a "Fine Tuned" Hematopoietic Regulation</i> , <i>Molecular Biology of Hematopoiesis</i> 5, pp. 463-470 (1996)	
	A13	RAMESHWAR, Pranela <i>et al.</i> , <i>Substance P (SP) Mediates Production of Stem Cell Factor and Interleukin-1 in Bone Marrow Stroma: Potential Autoregulatory Role for These Cytokines in SP Receptor Expression and Induction</i> , <i>Blood</i> , Vol. 86, No 2 (July 15), 1995: pp. 482-490	
	A14	RAMESHWAR, Pranela <i>et al.</i> , <i>Hematopoietic Regulation Mediated by Intearctions Among the Neurokinins and Cytokines</i> , <i>Leukemia and Lymphoma</i> , Vol. 28, pp. 1-10	

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A15	RAMESHWAR, Pranela <i>et al.</i> , <i>Release and Interleukin-1 and Interleukin-6 From Human Monocytes by Antihymocyte Globulin: Requirement for De Novo Synthesis</i> , Blood, Vol. 80 (November 15), 1992: pp. 2531-2538
A16	RAMESHWAR, Pranela <i>et al.</i> , <i>MOLECULE OF THE MONTH, Substance P: A Regulatory Neuropeptide for Hematopoiesis and Immune Functions¹</i> , Clinical Immunology and Immunopathology, Vol. 85, No. 2, November, pp. 129-133, 1997, Article No. II974446
A17	RAMESHWAR, Pranela <i>et al.</i> , <i>Induction of Negative Hematopoietic Regulators by Neurokinin-A in Bone Marrow Stroma</i> , Blood, Vol. 88, No. 1 (July 1), 1996: pp. 98-106
A18	RAMESHWAR, Pranela <i>et al.</i> , <i>Receptor Induction Regulates the Synergistic Effects of Substance P with IL-1 and Platelet-Derived Growth Factor on the Proliferation of Bone Marrow Fibroblasts¹</i> , The Journal of Immunology, 1997, 158: 3417-3424
A19	RAMESHWAR, Pranela <i>et al.</i> , <i>In Vitro Stimulatory Effect of Substance P on Hematopoiesis</i> , Blood, Vol. 81 (January 15), 1993: pp. 391-398
A20	REEVE, J.G. and Bleehen, N.M., [D-Arg ¹ , D-Phe ⁵ , D-Trp ^{7,9} , Leu ¹¹] Substance P Induces Apoptosis in Lung Cancer Cell Lines <i>in vitro</i> . Biochemical and Phophysical Research Communications 199: 1313-1319 (1994)
A21	SINGH, Deepreet <i>et al.</i> , <i>Increased expressions of preprotachykinin-1 and neurokinin receptors in human breast cancer cells: Implications for bone marrow metastasis</i> , PNA's, January 4, 2000, Vol. 97, no. 1, pp. 388-393
A22	THEODORSSON-NORHEIM, E. <i>et al.</i> , Isolation and characterization of neurokinin A, neurokinin A(3-10) and neurokinin A (4-10) from a neutral water extract of a metastatic ileal carcinoid tumour. Eur. J. Biochem 166:693-695 (1987)
A23	WEBBER, R.H. <i>et al.</i> , Bone marrow response to stimulation of the sympathetic trunks in rats. Acta. anat. 77:9297 (1970)
A24	WINKLER, A. <i>et al.</i> , Expression and characterization of the substance P (NK ₁) receptor in the rat pituitary and AtT20 mouse pituitary tumor cells. European Journal of Pharmacology 291: 51-55 (1995)

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